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Food and Drug Administratio
Atlanta District Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES

60 8th Street, N.E.
Atlanta, Georgia 30309

September 13, 2004

VIA FEDERAL EXPRESS

Charles A. Egeland, President
St. Simons Altama Sfd Inc. 48ss
5598 Altama Ave
Brunswick, GA 31525-2205

Warning Letter
04-ATL-20

Dear Mr. Egeland:

On July 14, 2004, FDA conducted an inspection of your seafood processing facility located at 5598 Altama Ave, Brunswick, Georgia. During that inspection, our investigator documented serious deviations from the seafood Hazard Analysis Critical Control Point (HACCP) regulations, contained in Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). These deviations cause your histamine-producing fish to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4), because the fish has been prepared, packed, or held under insanitary conditions whereby it may become contaminated with filth, or may have been rendered injurious to health. You can find the Act and the seafood HACCP regulations through links in FDA's home page at *www.fda.gov*.

The deviations of concern are as follows:

1. You must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for fresh shrimp to control the food safety hazard of undeclared sulfiting agents.

2. You must implement the record keeping system that you have listed in your HACCP plan for your histamine prone fish, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the "Receiving" critical control point to control the histamine formation hazard listed in your HACCP plan for histamine-prone fish. Our investigator identified several shipments of histamine prone fish received by your firm for which there were no records of the adequacy of ice on said fish.

We may take further action, without additional notice, if you do not promptly correct these violations. For instance, we may recommend that the United States bring a legal action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Karen Y. Dodson, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mrs. Dodson at (404) 253-1299.

Sincerely,

for Mary H. Woleske, Director
Atlanta District